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JONES DAY
555 SOUTH FLOWER STREET FIFTIETH FLOOR
LOS ANGELES, CA 90071

EXAMINER	
NASSER, ROBERT L	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL EVAN WEBBER

Appeal 2007-3177
Application 10/014,977
Technology Center 3700

Decided: June 30, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 4-6, 8-11, 13, 14, 17-22, 24-26, 29-34, 36, 37, and 39-42, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a method of analyzing alveolar breath. Claim 1 is illustrative:

> 1. A method of analyzing alveolar breath comprising:
>
> expiring breath through an analysis chamber;
>
> continuously monitoring a concentration of a first component of the breath by measuring the light energy absorbed by the first component as the breath is expired through the analysis chamber to determine when alveolar breath is in the analysis chamber; and
>
> triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath.

The Examiner relies on the following prior art references to show unpatentability:

Kiefer	US 3,830,630	Aug. 20, 1974
Phillipps	US 4,582,068	Apr. 15, 1986
Forrester	US 5,376,555	Dec. 27, 1994
Gustafsson	US 6,038,913	Mar. 21, 2000
Gratton	US 6,192,261 B1	Feb. 20, 2001

The rejections as presented by the Examiner are as follows:

1. Claims 1, 4-6, 8, 10, 11, 13, 14, 17, and 19 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Keifer, Forrester, and Phillipps.

2. Claims 1, 4-6, 8, 9, 11, 13, 14, 17, and 18 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Gustafsson, Keifer, Forrester, and Phillipps.

3. Claims 20-22, 24-26, 29, 31-34, 36, 37, 39, 40, and 42 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Keifer, Forrester, Phillipps, and Gratton.

4. Claims 20-22, 24-26, 29, 30, 32-34, 36, 37, 39, 41, and 42 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Gustafsson, Keifer, Forrester, Phillipps, and Gratton.

We reverse.

DISCUSSION

Claim Interpretation:

Claim 1 is drawn to a method of analyzing alveolar breath. The claimed method comprises three steps:

1. expiring breath through an analysis chamber;
2. *continuously monitoring* a concentration of a first component of the breath as the breath is expired through the analysis chamber to determine when alveolar breath is in the analysis chamber; and
3. based on the concentration of the first component in *only* the *immediately previous expired breath*, the spectroscopic measurement of at least one concentration of a second component of the breath is triggered, once the alveolar breath is in the analysis chamber.

In addition, claim 1 requires that the concentration of the first component is monitored by measuring the light energy absorbed by the first

component. Further, we interpret the phrase "immediately previous expired breath," as it appears in claim 1, to require that the concentration value of the first component that triggers the "measurement of a second component" to be variable not static. In this regard, we note that according to Appellants' Specification:

> [t]he threshold concentration value may be static or variable. A static threshold is set once at a particular level based upon the concentration profile of the first component and left at that level for subsequent breaths. Alternatively, the threshold may . . . *variably dependent on the concentration profile of previously expired breaths, and preferably the threshold is dependent upon the concentration profile of the immediately previous expired breath.*

(Spec. ¶ 0032 (emphasis added).)

Findings of Fact:

1. Kiefer teaches an apparatus and method for analyzing human breath (Kiefer 2: 44-45).

2. According to Kiefer, "[w]hile of broader significance, the invention is more specifically concerned with apparatus and methods for determining excess levels of alcohol consumption by humans" (Kiefer 1: 9-12).

3. Kiefer teaches that "air which has been fully inhaled into the lungs will reveal at least 4½% by volume CO_2 content" (Kiefer 3: 19-20).

4. Kiefer teaches that "a breath sample which has been fully inhaled and then exhaled will provide a true sample of alcohol not only in the breath but in the blood" (Kiefer 3: 21-23).

5. Kiefer teaches that "[f]or accurate measure of the alcohol content in the breath there must . . . be at least 4½% CO_2 by volume in the breath" (Kiefer 3: 27-29).

6. Kiefer teaches

> [i]n use, the described circuitry may, for example, be embodied in a hand-held device such as illustrated in FIG. **3**. The subject holds . . . and is directed to breath into the mouth piece . . . for three to five breaths. During this period, the device of the invention will both detect and quantitatively measure the CO_2 content of the captured breath by directing it over the CO_2 detector filament. . . . While the breath is also initially directed over the alcohol filament . . ., [this] filament . . . is essentially ineffective unless and until the CO_2 content reaches the 4½% level.

(Kiefer 3: 65 to 4: 1-9.)

7. Forrester teaches "the quantitative determination of the concentration of alcohol in a human breath sample for the purpose of determining blood alcohol concentration" (Forrester 1: 7-10).

8. Forrester teaches that "[c]arbon dioxide is a highly convenient reference gas because its concentration in ambient air is low . . . and its concentration in alveolar air is high (about 4.5 to 5.5%)" (Forrester (2: 51-55).

9. Forrester teaches that "if during exhalation alcohol is detected before carbon dioxide is detected, then that alcohol must have come from a part of the respiratory tract other than the alveoli and does not represent true blood alcohol levels" (Forrester 2: 57-61).

10. Forrester teaches that the optical measurement of carbon dioxide and alcohol concentration (Forrester 4: 62-67).

11. Phillipps teaches a system "for detecting the recurrence of a periodic physiological function" (Phillipps 2: 16-17).

12. Phillipps teaches that

> [p]hysiological functions typically are monitored by producing signals intended to represent these functions and processing such signals to extract useful data concerning the functions. . . . It is, however, difficult to avoid unintentionally receiving interferring [sic, interfering] components in such signals due to the functioning of adjacent organs, especially where non-invasive monitoring is undertaken.

(Phillipps 1: 11-22.)

13. Phillipps teaches a system wherein

> [t]hreshold crossing detecting means are provided for producing a recurrence signal representative of the recurrence of the physiological function in response at least in part to the filtered signal exceeding a threshold level; the threshold crossing detecting means being coupled to sense the minimum threshold level and operative to maintain the threshold level equal to or in excess of the minimum threshold level. Accordingly, the possibility of false triggering due to the artifact is substantially reduced in comparison to the prior art by clamping the threshold level at or above a minimum level derived from the unfiltered physiological signal, while permitting the detection of the desired physiological function only when the filtered signal crosses the thus clamped threshold level, making it substantially more difficult for the artifact to trigger the detection of the recurrence of the physiological function.

(Phillipps 2: 27-44.)

14. Gratton teaches "[t]he quantitative determination of various materials in highly scattering media such as living tissue may be determined in an external, photometric manner by the use of a plurality of light sources positioned at differing distances from a sensor" (Gratton Abstract).

15. Gustafsson teaches "[a] device for determining the level of nitric oxide in an exhaled airstream belonging to a living organism selected to have its lung function evaluated" (Gustafsson Abstract).

Analysis:

1. Claims 1, 4-6, 8, 10, 11, 13, 14, 17, and 19 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Keifer, Forrester, and Phillipps.

Based on the combined teachings of Keifer, Forrester, and Phillipps the Examiner finds that "it would have been obvious to modify Keifer . . . to use optical measurements" as taught by Forrester (Ans. 4). We agree. However, we disagree with the Examiner's conclusion that "it would have been obvious to modify . . . [the combination of Keifer and Forrester with the teachings of Phillipps] to update the threshold based on previous measurements, in order to allow the device to be fine tuned to each patient" (Ans. 4).

Both Keifer and Forrester teach the measurement of alcohol in the breath by a method that relies on a static concentration of at least 4½% CO_2 by volume in the breath (FF 1-9). Neither of these references teach that the concentration measurement of a second component of the breath (e.g., alcohol) is triggered based on the concentration of the first component in only the immediately previous expired breath as is required by Appellants' claimed invention. We disagree with the Examiner's assertion that Phillipps' method "for detecting the recurrence of a periodic physiological function" (FF 11) makes up for this deficiency in the combination of Keifer and Forrester.

Phillipps is concerned with avoiding artifacts in the measurement of the respiratory system caused by adjacent organs, e.g., cardiac events (FF 12 and 13). While it may be true that Phillipps updates the threshold "based on only the immediately previous patient measurement, to tune the device to the particular patient" (Ans. 4), the Examiner has failed to explain why a person using the apparatus and methods of Keifer and Forrester to, *inter alia*, measure alcohol concentration in the breath, would be concerned about respiratory artifacts caused by adjacent organs. Instead, both Keifer and Forrester expressly state that a static value of 4½% CO_2 by volume in the breath is the only threshold value necessary to trigger an accurate measurement of blood alcohol (FF 1-10).

We are not persuaded by the Examiner's assertion "that Phillipps is an example of what is well known in the medical monitoring field" (Ans. 6), and that "the issue is whether making the threshold variable is a patentable distinction given a fixed threshold" (Ans. 7).

> [A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007). On this record, the Examiner failed to identify a reason that would have prompted a person of ordinary skill in this art to modify the combined teachings of Keifer and Forrester with those of Phillipps to arrive at Appellants' claimed invention. We do not find it sufficient to simply state that such methodology was

known in the art with regard to other methods of monitoring other physiological states.

All of the remaining independent claims, claims 11, 20, and 32 require that the measurement of the second component of the breath be triggered, based on the concentration of the first component in only the immediately previous expired breath.

Accordingly, for the foregoing reasons, we reverse the rejection of claims 1, 4-6, 8, 10, 11, 13, 14, 17, and 19 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Keifer, Forrester, and Phillipps.

2. Claims 1, 4-6, 8, 9, 11, 13, 14, 17, and 18 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Gustafsson, Keifer, Forrester, and Phillipps.

The Examiner relies on the combination of Keifer, Forrester, and Phillipps as discussed above (Ans. 5). The Examiner relies on Gustafsson to teach "a method of measuring NO in alveolar air using spectrophotometric techniques" (*id.*). However, as Appellants point out "Gustafsson does not measure two breath components of breath, it measure[s] a single component" (App. Br. 7). The Examiner agrees (Ans. 8).

In sum, the Examiner has not identified and we do not find a teaching in Gustafsson that would make up for the deficiency in the combination of Keifer, Forrester, and Phillipps discussed above. Accordingly, we reverse the rejection of claims 1, 4-6, 8, 9, 11, 13, 14, 17, and 18 under 35 U.S.C. § 103 (a) as unpatentable over the combination of Gustafsson, Keifer, Forrester, and Phillipps.

3. Claims 20-22, 24-26, 29, 31-34, 36, 37, 39, 40, and 42 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Keifer, Forrester, Phillipps, and Gratton.

The Examiner relies on the combination of Keifer, Forrester, and Phillipps as discussed above. The Examiner relies on Gratton to teach "that it is known to multiplex signals of different wavelengths for measurement" (Ans. 6). The Examiner has not identified and we do not find a teaching in Gratton that would make up for the deficiency in the combination of Keifer, Forrester, and Phillipps discussed above. Accordingly, we reverse the rejection of claims 20-22, 24-26, 29, 31-34, 36, 37, 39, 40, and 42 under 35 U.S.C. § 103 (a) as unpatentable over the combination of Keifer, Forrester, Phillipps, and Gratton.

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The Examiner relies on the combination of Gustafsson, Keifer, Forrester, and Phillipps as discussed above. The Examiner relies on Gratton to teach "that it is known to multiplex signals of different wavelengths for measurement" (Ans. 6). The Examiner has not identified and we do not find a teaching in Gratton that would make up for the deficiency in the combination of Gustafsson, Keifer, Forrester, and Phillipps discussed above. Accordingly, we reverse the rejection of claims 20-22, 24-26, 29, 30, 32-34, 36, 37, 39, 41, and 42 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over the combination of Gustafsson, Keifer, Forrester, Phillipps, and Gratton.

CONCLUSION

In summary, we reverse the rejections of record.

REVERSED

cdc

JONES DAY
555 SOUTH FLOWER STREET FIFTIETH FLOOR
LOS ANGELES CA 90071